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http://dx.doi.org/10.17545/e-oftalmo.cbo/2017.81

Topical versus intracameral use of antibiotics in the prevention of endophthalmitis following cataract surgery

Uso tópico versus intracameral de antibiótico na profilaxia de endoftalmite pós-cirurgia de catarata

Uso tópico versus intracameral de antibiótico en la profilaxis de endoftalmitis postquirúrgica de catarata

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ABSTRACT

The intracameral use of antibiotics following cataract surgery significantly reduces the risk of postoperative endophthalmitis when compared to the pre- or postoperative use of topical antibiotics. The prophylactic use of this therapeutic regimen is a current practice in Europe and in a large number of countries around the world. It is not routinely followed in the US because no commercial antibiotic for intracameral use has been approved by the Food and Drug Administration. With this update on the topic, the Brazilian Society for Cataract and Refractive Surgery intends to show the positive impact of the intracameral use of antibiotics on reducing the rates of endophthalmitis following cataract surgery and highlights evidence of good outcomes that reinforce the safety and efficacy of this prophylactic therapeutic regimen.

Keywords:
Endophthalmitis;
Cataract;
Antibiotic Prophylaxis

RESUMO

O uso intracameral de antibiótico no final da cirurgia da catarata, em comparação com o uso tópico de antibiótico no pré e/ou pós-operatório, reduz significativamente o risco de endoftalmite pós-cirúrgica. O uso profilático desse regime terapêutico já é prática corrente na Europa e em número muito expressivo de países de outras regiões do mundo. Não é adotado de forma rotineira nos Estados Unidos porque lá não há preparação comercial de antibiótico para uso intracameral aprovada pelo *United States Food and Drug Administration* (FDA). A Sociedade Brasileira de Cirurgia Refrativa e Catarata (ABCCR/BRASCS), com esta atualização sobre o tema pretende mostrar o impacto positivo do uso intracameral de antibiótico na redução da taxa de endoftalmite pós-cirúrgica de catarata e, ao mesmo tempo, ressaltar as evidências de boa qualidade que reforçam a segurança e a eficácia do uso desse regime terapêutico profilático.

Palavras-Chave:
Endoftalmite;
Catarata;
Antibioticoprofilaxia

RESUMEN

El uso intracameral de antibiótico al término de la cirugía de catarata, si comparada al uso tópico de antibiótico en el pre y/o postoperatorio, reduce en gran manera el riesgo de la endoftalmitis postquirúrgica. El uso profiláctico de ese régimen terapéutico ya representa una práctica común y corriente en Europa y además en un número muy expresivo de países de otras regiones del mundo. No se adopta a modo rutinario en los Estados Unidos porque en ese país no hay preparación comercial de antibiótico para uso intracameral que sea aprobada por el United States Food and Drug Administration (FDA). Desde esa actualización acerca del tema, la Sociedad Brasileña de Cirugía Refractiva y Catarata (ABCCR/BRASCS, por sus siglas en portugués) tiene la intención de enseñar el impacto positivo del uso intracameral del antibiótico en el decrecimiento de la tasa de endoftalmitis postquirúrgica de catarata y, mientras eso, pone de relieve las evidencias de la buena calidad, que refuerzan la seguridad y la eficacia del uso de ese régimen terapéutico profiláctico.

Palabras Clave:
Endoftalmitis;
Catarata;
Profilaxis Antibiótica

Funding source: None
CEP Approval: Not applicable
Conflicts of interest: None
Received on: December 16, 2016
Approved on: December 16, 2016
Published on: March 31, 2017

How to cite: Alves MR, Victor G, Carricondo PC, Nose RM. Topical versus intracameral use of antibiotics in the prevention of endophthalmitis following cataract surgery. e-Oftalmo.CBO: Rev Dig Oftalmol. 2017;3(1):1-7. http://dx.doi.org/10.17545/e-oftalmo.cbo/2017.81

INTRODUCTION

Cataract surgery is the most common elective surgery in most countries in the Western world [1]. The improvement in visual acuity because of the surgery is responsible for considerable gains in the quality of life among patients [2]. However, even though the procedure is considered to be safe, complications may occur. The most unfavorable postoperative complication is endophthalmitis, an infectious condition caused by microorganisms introduced within the eye during or after the surgical procedure [1]. Endophthalmitis is an infection and can therefore be prevented by antibiotic treatment. However, there is still a debate regarding which antibiotic and which method of application are most effective against endophthalmitis following cataract surgery.

Using antibiotics to prevent endophthalmitis following cataract surgery

A systematic review of the literature and a meta-analysis were performed based on the MEDLINE, CINAHL, Cochrane Library, and EMBASE databases. On the one hand were one randomized clinical trial and 17 observational studies on the prophylactic effect of the intracameral use of antibiotics; on the other hand were one randomized clinical trial and one observational study on the prophylactic effect of the use of antibiotics on the incidence of endophthalmitis following cataract surgery [1]. This systematic review and meta-analysis produced moderate- to high-quality evidence of a marked reduction in the risk of endophthalmitis with the intracameral use of cefazolin, cefuroxime, and moxifloxacin and no effects with the intracameral use of vancomycin [1]. The authors found no studies reporting prophylactic effects with the topical use of antibiotics [1]. On an average, endophthalmitis occurred in 1 out of 2,855 surgeries involving the intracameral use of antibiotics and in 1 out of 485 surgeries without the intracameral use of antibiotics, which is a highly significant difference ($p < 0.00001$). The authors concluded that the intracameral use of antibiotics is the best choice for preventing endophthalmitis, and they found no evidence of topical antibiotic therapy preventing endophthalmitis following cataract surgery [1]. It can be deduced that two to four cases of endophthalmitis in every 1,000 surgeries can be prevented with the intracameral use of cefuroxime. There is no documented effect of the topical use of antibiotics on the prevention of endophthalmitis, and the topical use of antibiotics may be associated with the selection of resistant bacterial strains. For these reasons, the topical use of these antibiotics is not recommended [1].

Although the rates of endophthalmitis following cataract surgery are low (0.04%–0.41%) [3], the fact that millions of patients undergo cataract surgery annually makes endophthalmitis a significant public health issue [4].

Jabbarvand et al. [5] reported an incidence of 0.023% of endophthalmitis in more than 480,000 cataract surgeries performed at the Farabi Eye Hospital from 2006 to 2014. According to the authors, the preoperative (topical or systemic) or postoperative (topical or subconjunctival) use of antibiotics reduces the risk of endophthalmitis by 40%–50%. In addition, the intracameral use of cefuroxime was 100% effective in preventing endophthalmitis in this study.

Rudnisky et al. [6] calculated the incidence of endophthalmitis following cataract surgery over an 8-year period, during which more than 75,000 cataract surgeries were performed. In their study, the rate of endophthalmitis was influenced by neither the intracameral (vancomycin or moxifloxacin) nor the subconjunctival use of antibiotics (cefazolin, gentamicin, or cefuroxime); however, the postoperative use of moxifloxacin was associated with a lower rate of endophthalmitis ($p = 0.029$). A multivariate analysis demonstrated that the odds ratio (OR) of endophthalmitis was lower with the topical postoperative use of second- and fourth-generation fluoroquinolones ($p = 0.02$ and $p = 0.008$, respectively).

Gower et al. [7] performed a systematic review to evaluate the effects of the preoperative use of antibiotics on the prevention of endophthalmitis following cataract surgery. The authors selected four studies with a total of 100,876 adults and 131 cases of endophthalmitis. The heterogeneity of the study designs and the large variation in antibiotic regimens made a meta-analysis impossible. The evaluated interventions included the use of vancomycin and gentamicin in an irrigation solution versus the use of an irrigation solution alone, intracameral use of cefuroxime versus topical use of levofloxacin, and the topical use of chloramphenicol sulfonamide versus the topical use of the antibiotic alone.

In their 2007 study, the European Society of Cataract and Refractive Surgeons (ESCRS) found that the intracameral use of placebo presented a 4.9% higher risk of endophthalmitis relative to the intracameral use of cefuroxime or moxifloxacin, which may be understood as an 80% reduction in the rate of endophthalmitis with the intracameral use of antibiotics [8]. It is important to note that endophthalmitis is rare following cataract surgery, but it is potentially devastating to the patient's vision [9,10].

Herrinton et al. [11] performed a longitudinal, observational, and controlled cohort study of approximately 315,000 phacoemulsification procedures to identify which prophylactic regimen was the most effective. They compared the intracameral use of antibiotics (cefuroxime or moxifloxacin) to the topical use of antibiotics (gatifloxacin, ofloxacin, polymyxin-trimethoprim, moxifloxacin, neomycin, gentamicin, or tobramycin). The authors found 215 cases of endophthalmitis (0.07% or 0.7 per 1,000 cases). The intracameral use of antibiotics was more effective than the topical use of a single antibiotic [OR: 0.58; confidence interval (CI): 0.38–0.91]. The combination of intracameral antibiotics and topical applications of gatifloxacin or moxifloxacin was not more effective than the intracameral use alone (OR: 1.63; CI: 0.48–5.47). When compared to the topical use of other antibiotics, topical gatifloxacin reduced the risk of endophthalmitis by 42%; neomycin, gentamicin, and tobramycin were less effective (OR: 1.97; CI: 1.17–3.31). The risk of endophthalmitis in patients not administered with intracameral antibiotics in this study was lower than that in other studies (0.044% risk of endophthalmitis in the intracameral group and 0.070% risk in the topical group). These data were consistent with those of the ESCRS study (0.05% risk of endophthalmitis in the intracameral group and 0.35% risk in the control group) [8]. The authors concluded that the intracameral use of antibiotics was more effective for preventing endophthalmitis following cataract surgery than the topical use of antibiotics alone [11]. The topical use of antibiotics did not render the intracameral regimen any more effective. The authors found no convincing evidence of a difference in efficacy between intracameral moxifloxacin and cefuroxime. In this study, moxifloxacin was used directly and concentrated or diluted in equal parts of balanced saline solution to obtain a concentration of 250 µg per 0.1 ml. The authors reported the intracameral application of cefuroxime in 13 eyes (11 patients), with an error of formulation of 9 mg, which resulted in acute macular edema that was resolved within 1 week with no further complications [12]. That was the first study to report an association between the intracameral use of cefuroxime and adverse effects. Increased resistance to fluoroquinolones may support the use of cefuroxime, particularly in patients exposed to fluoroquinolones in the past. The intracameral injection of any antibiotics may be less subject to the occurrence of resistance as the antibiotics are administered as a single concentrated dose in a relatively confined space in contrast to the topical use of antibiotics, which include repeated and less effective low doses of the drug [11]. Vancomycin has also been used in intracameral injections to prevent infection and has been found to be effective against gram-positive bacteria. However, concerns over resistance have limited its use to approximately 1% of patients who are allergic both to penicillin/cephalosporins and fluoroquinolones [13]. In their conclusion, the authors recommend the intracameral injection of cefuroxime or moxifloxacin in all phacoemulsification surgeries. The use of a topical agent alone is less effective and is also subject to errors in prescription and a lack of patient compliance. Topical aminoglycoside antibiotics are less effective in preventing endophthalmitis [13].

Using intracameral antibiotics to prevent endophthalmitis following cataract surgery

The intracameral use of antibiotics following cataract surgery has become a common practice in Europe and is even mandatory in many countries. Despite the scientific recognition of the efficacy of this practice, it is not routinely used in the United States. The greatest barrier to its adoption is the lack of approval by the Food and Drug Administration (FDA) of a commercial antibiotic for intracameral use [4].

Three large observational studies (one in the US [14], one in India [11] and one in Iran [5]) involved close to 640,000 patients and demonstrated a clear association between the intracameral use of antibiotics (cefuroxime, cefazolin, or moxifloxacin) following cataract surgery and a reduction in postoperative endophthalmitis [4]. These findings further confirm and support the evidence gathered on this topic. Similar findings were also obtained in a multicenter study carried out by ESCRS [4,8]. These new studies, considered in conjunction with previously published research [15,16,17,18,19,20,21,22,23,24], show that the topical use of antibiotics resulted in 2.66 times greater risk of postoperative endophthalmitis relative to the intracameral use of antibiotics [4].

The efficacy of the intracameral use of antibiotics has been recognized by the American Academy of Ophthalmology (AAO). Nevertheless, the topical use of antibiotics is more common in the US [4], despite the fact that this practice has almost been completely phased out in Europe [4]. The intracameral use of antibiotics has become universal in Sweden. In France and Denmark, government authorities and local ophthalmology societies specifically recommend the intracameral use of antibiotics [4].

The antibiotics produced for intracameral use may be associated with new risks for patients. A recent editorial [25] raised questions regarding the risks of incorrect antibiotic formulation for intracameral use, but it did not identify any adverse effects associated with the commercial product formulated for intracameral use. The editorial also noted the importance of monitoring the risk of administering

intracameral antibiotics leading to bacterial resistance. Furthermore, physicians must also be aware of the possibility of errors when choosing the diluent, dilution levels, or product sterilization. For example, the preparation for the intracameral use of cefuroxime, initially designed for intravenous use, requires dilution with a saline solution and has created a series of risks that can be amplified when the content of the antibiotic container is divided for use among various patients. The same risk occurs when a saline solution is divided, particularly if these operations occur in an environment with laminar air flow, which is usual in operating rooms [25].

Based on the results of approximately 3 million cataract surgeries in the US annually, the adoption of the intracameral use of antibiotics may potentially save more than 2,000 eyes per year from the negative impact of postoperative endophthalmitis [4].

The intracameral use of antibiotics to prevent infection following cataract surgery and other intraocular surgeries began in 2002 [26]. The multicenter, prospective, randomized study by ESCRS [8] which evaluated the prophylactic use of intracameral versus topical antibiotics, considered 16,000 patients and found 4.92 times more risk of endophthalmitis with the topical use of antibiotics. This result made the intracameral use of antibiotics widespread in Europe despite the lack of an approved intracameral antibiotic formulation. Later, the commercial formulation of cefuroxime for intraocular use was accepted across the European Union. It is important to note that the fixed price of cefuroxime was substantially lower than that of antibiotic eye drops [4].

The main limitation of the intracameral use of antibiotics in the US is the lack of approval by FDA of a commercial antibiotic for intracameral use [4]. American ophthalmologists are dissuaded from the intracameral use of antibiotics based on the risk of legal and financial consequences because the product is not approved for this use and would therefore need to be used off-label. As previously mentioned, the preparation of the product in the operating room has many risks. In the US, despite the existence of pharmacies licensed to supply sterile products, they are requested only for special patients. Recently, FDA inspected 28 pharmacies authorized to produce sterile medications and identified violations in each one of them [27]. Javitt [4] also reported the following barriers: a) no commercial sponsor has presented FDA with a new drug application, b) minimum financial return is expected, and c) there is a need for guidelines to regulate controlled safety and efficacy studies of the actual drug that the manufacturer plans to sell. The personal opinions of the members of FDA regarding the merits and limitations of ESCRS study [5] include the following: a) the rate of endophthalmitis in the control group was much higher than that expected and exceeded the rate reported in other studies from the European Union, b) there was a potential for bias because of the fact that the study was not blinded, c) the data were not adjusted for the possibility of false positives, d) the study was prematurely closed and the analysis of the results considered multiple subgroups, and e) there was a low number of incident cases. Based on these limitations, FDA recommended that another randomized clinical trial be performed with the commercially manufactured product to demonstrate significant reduction in the rate of endophthalmitis [4]. The costs of a study with these characteristics are likely to exceed 10,000 USD per patient and 350 million USD for the sponsor, in addition to the negative expectations regarding return on investment.

There is currently a universal adoption of the prevention of endophthalmitis using intracameral injections of antibiotics following cataract surgery and other intraocular surgeries. This practice has been adopted in Europe and in a large number of countries. The challenge is in the hands of AAO and FDA, which have the joint responsibility of offering American patients a better endophthalmitis prevention regimen following cataract surgery as soon as possible.

In Brazil, the intracameral use of antibiotics following cataract surgery is also an off-label procedure. In order to facilitate the acceptance of this practice in the country, the Brazilian Society of Cataract and Refractive Surgery is hereby submitting this letter and information on this topic to the Brazilian Federal Council of Medicine for it to issue an opinion on the prevention of endophthalmitis through the intracameral use of antibiotics in intraocular surgeries.

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